

which a fluid from an external fluid source can be introduced into said probe and pass through said probe into the duct when said probe is positioned within the breast duct.

REMARKS

The Office Action of December 17, 2002 has been received and considered. In the Office Action, the claims were rejected under either 35 U.S.C. §102(b) or under 35 U.S.C. §103(a) based on U.S. Patent No. 6,413,228 to Hung et al., alone or in combination with other publications.

Claim 1 has been amended. Claims 1-13, 26 and 27 remain pending. Reconsideration of the application is requested. No new matter has been added.

An aspect of the present invention relates to a device that is introduced into a breast duct in order to obtain a ductal fluid sample from within the duct. The device has a diameter that is sized to allow the device to enter the breast duct, contact the epithelial lining of the duct and collect fluid from within the breast duct. Contrary to conventional devices that can be positioned within a breast duct, the device according to the present invention does not include any fluid introduction ports or connections that would permit a fluid to be introduced into the probe and, ultimately the breast duct through the probe, while the probe is positioned within the duct.

Claims 1, 3-5, 12, 26 and 27 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,413,228 to Hung et al. (hereinafter “Hung”). However, this patent to Hung does not qualify as prior art under 35 U.S.C. §102(b), which clearly states that an invention is not novel if it was described in a printed publication “more than one year prior to the date of the application for patent” (emphasis added). The instant application was filed before the issue date

of the patent to Hung. Specifically, the instant application was filed in the U.S. Patent and Trademark Office on July 26, 2001 and claims benefit of provisional patent application No. 60/221,654 filed on July 28, 2000. The patent to Hung issued on July 2, 2002. As can be seen from a comparison of the dates, the issue date of the Hung patent is over eleven months after the filing date of the instant application and almost two years after the filing date of the priority provisional application. As a result, the patent to Hung cannot qualify as prior art to the instant application under 35 U.S.C. §102(b) and the rejection must be withdrawn. If the rejection is maintained and an Advisory Action issued, the Applicant requests that authority for this position be provided with the Advisory Action and an interview be granted to the undersigned.

Nevertheless, the patent to Hung fails to disclose the device recited in claim 1. Specifically, the figures of the Hung patent that were relied upon in the Office Action (Figures 4A and 4B) clearly teach that a fluid is introduced into the illustrated ductal access tube 12 and then into the breast duct. Specifically, the fluid (1) is introduced through an opening at the proximal end of the access tube 12 (left side of Figs. 4A, 4B) and (2) enters the duct as it exits the distal end 14 of the access tube 12. The patent to Hung does not disclose a probe that is free of an opening through which a fluid from an external fluid source can be introduced into said probe and pass through said probe into the duct when said probe is positioned within the breast duct. To the contrary, the patent to Hung expressly discloses the presence of such an opening. Therefore, the patent to Hung does not anticipate claims 1-13, 26 and 27 because it fails to disclose each and every recited element of these claims. Withdrawal of the rejection is requested.

Claims 2, 6 and 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hung in view of U.S. Patent No. 4,635,488 to Kremer that discloses a device for the non-invasive collection of body fluids. Kremer is relied upon to teach the concept of a distal portion of a device carrying particular materials that exhibit specific characteristics, such as absorption.

It was suggested in the Office Action that it would have been obvious to modify the access tube 12 of Hung that introduces a lavaging fluid into a duct to arrive at the probe recited in claims 2, 6 and 7 in view of the teachings of Kremer. However, modifying the access tube of Hung to arrive at the recited probe would not have been obvious for such modifications would clearly destroy the purpose and use of the Hung access tube.

As clearly set forth in the patent to Hung, the access tube 12 receives a lavage fluid and introduces this fluid into a breast duct so that the breast duct can be lavaged. In order to arrive at the recited probe, the access tube of Hung would have to be modified (1) to not include its disclosed opening for receiving a lavage fluid and (2) to include an absorbent material on the distal end. Both of these alleged modifications would clearly destroy the express teachings of Hung because they would both prevent the disclosed lavage fluid from being introduced into the duct. Hence, the asserted combination would not have been obvious to the ordinary artisan because they contradict the express teachings of Hung. Withdrawal of the rejection is requested.

Claim 8 was rejected under 35 U.S.C. §103(a) as being unpatentable over Hung in view of U.S. Patent No. 4,635,488 to Kremer and further in view of Hung. The additional Hung disclosure is relied upon to disclose that ductal fluids comprise indicia and markers. It was asserted that it would have been obvious to modify the modified fluid collecting device of Hung

and Kremer to arrive at a device that analyzes substances found in the ductal fluid sample. However, as discussed above, the combination of Hung and Kremer fails to disclose the device as recited in claim 1. The additional Hung disclosure does not cure the deficiencies of the Hung and Kremer combination. Therefore, the combination of Hung, Kremer and Hung would not have been obvious because it fails to arrive at the device recited in claim 1. Withdrawal of the rejection is requested.

Claims 9 and 10 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hung in view of U.S. Patent No. 5,844,251 to MacDonald et al., alone or further in view of Hung. MacDonald is relied upon to disclose a probe comprising MEMS. It was asserted that it would have been obvious to modify the fluid collecting device of Hung to create a probe with MEMS that is used to scan surfaces of a breast duct in order to measure surface configurations on a micron scale. However, like Kremer, MacDonald does not teach what Hung lacks.

As discussed above, it would not have been obvious to the ordinary artisan to modify the ductal access tube of Hung that is used to introduce a fluid and retrieve a fluid from within a duct to arrive at the recited device that is free of an opening through which a fluid from an external fluid source can be introduced into said probe and pass through said probe into the duct when said probe is positioned within the breast duct. Additionally, MacDonald does not disclose a device that is sized for fitting within a breast duct, that samples ductal fluid and that is free of the opening for receiving a fluid as recited in claim 1. Therefore, nothing in the disclosure of MacDonald would have motivated one of ordinary skill in the art to modify the ductal access

tube of Hung to arrive at the ductal fluid collection device recited in the pending claims.

Withdrawal of the rejection is requested.

Claim 11 was rejected under 35 U.S.C. §103(a) as being unpatentable over Hung in view of U.S. Patent No. 5,263,926 to Wilk. The Wilk disclosure is relied upon to teach a probe with an externally applied anesthetic. It was asserted that it would have been obvious to modify the fluid collecting device of Hung to include an externally carried anesthetic. However, like Kremer, the teachings of Wilk would not have motivated one of ordinary skill in the art to modify the ductal access tool of Hung to include a probe that is free of an opening through which a fluid from an external fluid source can be introduced into said probe and pass through the probe into the duct when said probe is positioned within the breast duct as recited in claim 1. Therefore, the combination asserted in the Office Action would not have been obvious in view of the teachings of Wilk. Withdrawal of the rejection is requested.

Claim 13 was rejected under 35 U.S.C. §103(a) as being unpatentable over Hung in view of U.S. Patent No. 5,382,228 to Nita et al. The Nita patent is relied upon to disclose the use of shape memory materials. However, this patent only discloses the use of shape memory materials for an ultrasonic probe. It was asserted that it would have been obvious to modify the fluid collecting device of Hung to include the shape memory material of the ultrasonic transmitting wire disclosed in the patent to Nita.

The patent to Nita does not disclose a fluid collection device as recited in the pending claims. Additionally, it does not provide a teaching or motivation for modifying the Hung ductal access tube to be free of an opening through which a fluid from an external fluid source can be

introduced into said probe and pass through the probe into the duct when said probe is positioned within the breast duct as recited in claim 1. Therefore, the combination of Hung and Nita would not have been obvious because the resulting combination would not arrive at the device recited in claim 1. Withdrawal of the rejection is requested.

As discussed above, the finality of the outstanding Office Action cannot be maintained because the patent to Hung is clearly not prior art to the pending claims under 35 U.S.C. §102(b). Therefore, withdrawal of the finality of the outstanding Office Action and entry of the amendments to claim 1 is requested. These amendments do not raise new issues and they place the application in better position for immediate appeal.

For all of the above-discussed reasons, claims 1-13, 26 and 27 are allowable over the prior art. Applicant respectfully submits that the application is now in condition for allowance. A notice to this effect is earnestly solicited.

If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a conference with Applicant's attorney, the Examiner is invited to contact Applicant's attorney at the number noted below.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Twice Amended) A device for collecting breast duct fluid from within a breast duct in order to detect breast cancer or precancer comprising:
a probe having a diameter sized to penetrate a breast duct and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis, and wherein said probe is free of an opening through which a fluid from an external fluid source can be introduced into said probe and pass through said probe into the duct when said probe is positioned within the breast duct [a connection for a fluid source or lumen].